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Obesity and surgical complications of pancreaticoduodenectomy: An observation study utilizing ACS NSQIP☆

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ABSTRACT

Background: An estimated 38% of US adults are obese. Obesity is associated with socioeconomic disparities and increased rates of comorbidities, and is a known risk factor for development of pancreatic cancer. As a fourth leading cause of death in the United States, pancreatic cancer is commonly treated with a pancreatico-duodenectomy (PD), or Whipple procedure. Data regarding the effects of obesity on post-operative complication rate primarily comes from specialized centers, however the results are mixed. Our aim is to elucidate the effects that obesity has on outcomes after PD for pancreatic head cancer using a national prospectively maintained clinical database.

Method: The 2010–2015 American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) Participant Use Files (PUF) were used as the data source. We identified cases in which PD was performed (CPT code 48150) in the setting of a postoperative diagnosis of pancreatic cancer (ICD9 code 157.0). We excluded cases that had emergency admissions, BMI ≤ 18.5 kg/m^2, intraoperative wound classification of III or IV, and disseminated cancer. Cases with missing BMI, preoperative albumin, operative time, LOS data were also excluded. Multiple imputation for missing sex, race, functional status, and ASA classification using chained equations was performed.[16] Patients that had BMI ≥ 30 kg/m^2 were considered obese, and patients with BMI <30 kg/m^2 were used as control.

Results: 3484 patients underwent pancreaticoduodenectomy for pancreatic cancer. 860 patients were identified as obese. Propensity score analysis was performed matching age, sex, race, functional status, presence of dyspnea, diabetes, hypertension, acute renal failure, dialysis dependence, ascites, steroid use, bleeding disorders, history of chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), weight loss, American Society of Anesthesiologists (ASA) classification, and preoperative albumin levels. After matching, obese patients had higher risk of 30-day postoperative complications compared to control, including organ space wound infections (OR 1.38, 95% CI 1.07–1.79, $p = 0.0128$), returning to the operating room (OR 1.39, 95% CI 1.01–1.91, $p = 0.0461$), failure to extubate for greater than 48 h (OR 1.60, 95% CI 1.09–2.34, $p = 0.0153$), death (OR 1.68, 95% CI 1.01–2.78, $p = 0.0453$), septic shock (OR 2.22, 95% CI 1.46–3.38, $p = 0.0002$), pulmonary embolism (OR 2.42, 95% CI 1.07–5.45, $p = 0.0332$), renal insufficiency (OR 2.67, 95% CI 1.33–5.38, $p = 0.0058$). Sensitivity analysis yielded similar results with the exception of risk for return to the operating room, death, and pulmonary embolism, $P > .05$.

Conclusion: In this large observational study using a national clinical database, obese patients undergoing PD for head of pancreas cancer had increased risk of postoperative complications and mortality in comparison to controls.

Introduction

Pancreatic cancer is the fourth leading cause of cancer related death in the United States with a five year survival rate of 7%.[1] At

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this time, pancreaticoduodenectomy (PD) is the only potentially curative treatment for pancreatic cancer. Multiple risk factors have been associated with the development of pancreatic cancer, including body mass index (BMI), smoking, diabetes, family history, and identifying as African American.[2]

Among these risk factors, obesity affects approximately 38% of the US population and the incidence continues to rise.[3] Obesity, which is defined as a BMI $\geq$30 kg/m^2, and further stratified into class I (30–34.9 kg/m^2), class II (35.0–39.9 kg/m^2), and class III (>40.0 kg/m^2), has been linked to increased risk of developing pancreatic cancer.[4,5] The impact of obesity in pancreatic cancer is pervasive; there is evidence linking obesity to decreased survival following pancreaticoduodenectomy (PD), with obese patients having higher rates of node-positive disease in patients undergoing PD with curative intent.[6]

Although the mortality rate following PD has dramatically decreased in the modern era, morbidity rates range from 18 to 61% even in high volume centers.[7–9] The Literature regarding the effects of obesity on postoperative outcomes following PD for pancreatic cancer is conflicted. Studies have suggested that obesity does not increase morbidity in elective general surgical cases, which is also supported by data from the surgical oncology literature.[10,11] On the other hand, multiple single institutional studies, with differing definitions of obesity, have linked obesity with complications such as intraoperative bleeding, increased development of pancreatic fistulas, and increased length of stay (LOS) after PD.[12–15]

Given the conflicting data, and as surgeons will increasingly encounter obese patients, the objective of our study was to determine whether obesity is associated with worse postoperative outcomes following PD for pancreatic cancer using a national clinical database. We hypothesized that patients with obesity would have higher rates of postoperative complications in comparison to those who were not obese.

Methods

Patients and data

The 2010–2015 American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) Participant Use Files (PUF) were used as the data source. As the data was obtained from a publicly available, deidentified source, Institutional Review Board exemption was obtained for this study. We identified cases in which PD was performed (CPT code 48150) in the setting of a postoperative diagnosis of pancreatic cancer (ICD9 code 157.0). We excluded cases that had emergency admissions, BMI $\leq$18.5 kg/m^2, intraoperative wound classification of III or IV, and disseminated cancer. Cases with missing BMI, preoperative albumin, operative time, LOS data were also excluded (see Table 5). Multiple imputation for missing sex, race, functional status, and ASA classification using chained equations was performed.[16] Patients that had BMI $\geq$30 kg/m^2 were considered obese, and patients with BMI <30 kg/m^2 were used as control.

Statistical analysis

Univariate analysis was performed comparing postoperative outcomes between obese patients to control. Wilcoxon Rank Sum test was used for continuous variables, while Fisher's test and Chi-square test were used as appropriate for categorical variables. Propensity score analysis was then performed by matching the obese to control cohort. We then matched over patient characteristics including age, sex, race, functional status, presence of dyspnea, diabetes, hypertension, acute renal failure, dialysis dependence, ascites, steroid use, bleeding disorders, preoperative transfusion of red blood cells, history of chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), weight loss, American Society of Anesthesiologists (ASA) classification, and preoperative albumin levels. We employed nearest-neighbor matching without replacement using a caliper of 0.1 with a ratio of 3:1.[17–19] Quality of match was assessed using the absolute standardized mean difference with a goal of $\leq$0.2.[20] Post-match analysis was conducted for categorical outcomes of interest using conditional logistic regression and for continuous variables using the Wilcoxon-Rank Sum test. We performed sensitivity analysis by re-performing the propensity score matching with the same parameters except that we used a caliper of 0.01, to further reduce bias of covariates, and then performing post-match analysis.[21] Statistical analysis was performed using the R programming language version 3.4.1.[22]

Results

Patient characteristics

A total of 3484 cases met criteria, of which 860 cases were performed in obese individuals. Significant differences in the baseline characteristics were noted between the control and obese population. The obese population, compared to control, was younger (mean 64.1 vs 66.9 years, $P < 0.001$), had a higher proportion of females (52.3% vs 46.6%, $P = 0.004$), African Americans (11.7% vs 8.2%, $P < 0.001$), had higher rates of insulin dependent diabetes (20.7% vs 13.8%, $P < 0.001$), dyspnea with moderate exertion (8.4% vs 5.1%, $P = 0.002$), hypertension requiring medications (68.0% vs 53.5%, $P < 0.001$), and were more likely to be ASA class III (74.4% vs 68.3%, $P = 0.002$). The obese population was less likely to have a history of weight loss compared to control (14.3% vs 22.3%, $P < 0.001$). There was no difference in the preoperative albumin levels between the obese and control groups (mean 3.65 vs 3.67 mg/dL, $P = 0.41$). See Table 1.

Univariate analysis

Comparison of unmatched obese patients to control showed that obese patients had greater operative time (median 398.0 min, IQR 320.0–491.2) compared to those in the control group (median 366.0, IQR 287.0–381.0), $P < 0.001$. Obese patients also had higher rates of 30-day postoperative morbidity including organ space wound infections (11.5% vs 8.5%, $P = 0.01$), failure to extubate after 48 h (5.9% vs 3.2%, $P < 0.001$), pulmonary embolism (1.4% vs 0.6%, $P = 0.04$), renal insufficiency (2.2% vs 0.7%, $P < 0.001$), postoperative septic shock (5.3% vs 2.5%, $P < 0.001$). Furthermore, 30-day mortality was higher in the obese group compared to control (3.3% vs 2.0%, $P = 0.04$). See Table 2.

Propensity score model

After performing propensity score matching, 843 obese patients were matched to 1928 control patients. The two groups were well matched across all patient characteristics with an absolute standardized difference $\leq$0.2. Table 1 demonstrates the patient characteristics both pre- and post-match.

Post-match analysis again showed that operative time was significantly longer in the obese group compared to control (median 397 vs 367 min, $P < 0.001$). There was no difference in overall LOS (median 9.0 vs. 9.0 days, $P = 0.39$). The matched obese group had higher risk of 30-day postoperative complications, including organ space wound infections (OR 1.38, 95% CI 1.07–1.79, $P = 0.01$), returning to the operating room (OR 1.39, 95% CI 1.01–1.91, $P = 0.05$), failure to extubate after 48 h (OR 1.60, 95% CI 1.09–2.34,

Table 1
Patient characteristics of obesity and control before and after propensity score matching.

Characteristic	Overall Cohorts			Matched Cohorts		
	Control (n = 2624)	Obese (n = 860)	Absolute Standardized Difference	Control (n = 1928)	Obese (n = 843)	Absolute Standardized Difference
Age, years, mean (SD)	66.9 (10.0)	64.1 (10.0)	2.7804	65.6 (10.5)	64.4 (9.7)	0.0761
Sex (%)						
Female	1223 (46.6)	450 (52.3)	0.0572	950 (49.3)	437 (51.8)	0.0
Male	1401 (53.4)	410 (47.7)	0.0572	978 (50.7)	406 (48.2)	0.0
Race (%)						
Asian	75 (2.8)	4 (0.4)	0.0239	15 (7.78)	4 (0.47)	0.0012
African American	216 (8.2)	101 (11.7)	0.0351	184 (9.54)	96 (11.4)	0.001
Native Hawaiian/Pacific Islander	7 (2.6)	0 (0.0)	0.0027	0 (0.0)	0 (0.0)	0.0
White	2317 (88.3)	751 (87.2)	0.0097	1725 (89.5)	740 (87.8)	0.0014
Diabetes (%)						
None	1929 (73.5)	539 (62.7)	0.1084	1324 (68.7)	534 (63.3)	0.0022
Non-Insulin Dependent	332 (12.7)	143 (16.6)	0.0398	283 (14.7)	138 (16.3)	0.0
Dyspnea (%)						
None	2485 (94.7)	786 (91.4)	0.0331	1804 (93.6)	773 (91.7)	0.0018
Moderate Exertion	135 (5.1)	73 (8.4)	0.0334	122 (6.3)	69 (7.9)	0.0016
Functional Status (%)						
Partially Dependent	31 (1.18)	14 (0.6)	0.0045	27 (1.4)	12 (1.4)	0.0006
Totally Dependent	4 (0.15)	1 (0.11)	0.0004	4 (0.2)	1 (0.12)	0.0006
Smoking (%)	523 (19.9)	150 (17.4)	0.0249	380 (19.7)	149 (17.7)	0.0105
History of COPD (%)	119 (4.5)	48 (5.6)	0.0105	104 (5.4)	46 (5.5)	0.0038
History of CHF (%)	8 (0.3)	2 (0.23)	0.0007	4 (0.2)	2 (0.24)	0.0006
Hypertension (%)	1403 (53.5)	585 (68.0)	0.1456	1186 (61.6)	569 (67.5)	0.0113
Renal Failure (%)	3 (0.11)	1 (0.11)	0.0	3 (0.16)	1 (0.12)	0.0004
Dialysis Dependent (%)	4 (0.15)	1 (0.11)	0.0004	3 (0.16)	1 (0.12)	0.0002
Ascites (%)	10 (0.38)	3 (0.34)	0.0003	8 (0.41)	3 (0.36)	0.0
Steroid Use (%)	57 (2.2)	18 (2.1)	0.0008	42 (2.1)	17 (2.0)	0.0004
History of Weight Loss (%)	586 (22.3)	123 (14.3)	0.0803	334 (17.3)	122 (14.5)	0.0043
Bleeding Disorder (%)	70 (1.5)	25 (2.9)	0.0024	51 (2.6)	25 (2.9)	0.0002
Preoperative Transfusion (%)	26 (0.1)	6 (0.6)	0.0029	15 (0.8)	6 (0.71)	0.001
ASA Class (%)						
Class II	633 (24.1)	157 (17.3)	0.0587	408 (21.2)	156 (18.5)	0.0071
Class III	1793 (68.3)	640 (74.4)	0.0609	1377 (71.4)	626 (74.3)	0.0051
Class IV	182 (6.9)	60 (7.0)	0.0004	134 (6.95)	58 (6.8)	0.003
Class V	0 (0.0)	0 (0.0)	0.0	0 (0.0)	0 (0.0)	0.0
Prealbumin, mg/dL, mean (SD)	3.7 (0.62)	3.6 (0.64)	0.0201	3.7 (0.6)	3.6 (0.43)	0.0043

n: Sample Size, SD: Standard Deviation, COPD: Chronic Obstructive Pulmonary Disease, CHF: Congestive Heart Failure, ASA: American Society of Anesthesiologist Classification.

Table 2
Univariate analysis of unmatched obesity and control.

Characteristic	Control (n = 2624)	Obese (n = 860)	p-Value
Operative Time, median minutes (SD)	366.0 (136.1)	398.0 (136.6)	<0.0001
Length of Stay, median days (SD)	9.0 (8.7)	9.0 (9.3)	0.2836
Superficial Wound Infection (%)	223 (8.5)	83 (9.7)	0.3335
Deep Space Wound Infection (%)	57 (2.2)	28 (3.3)	0.0758
Organ Space Wound Infection (%)	224 (8.5)	99 (11.5)	0.0110
Dehiscence (%)	31 (1.2)	17 (2.0)	0.0918
Pneumonia (%)	106 (4.0)	39 (4.5)	0.5942
Unplanned Intubation (%)	105 (4.0)	44 (5.1)	0.1919
Failure to Extubate >48 Hours (%)	85 (3.2)	51 (5.9)	0.0006
Pulmonary Embolism (%)	16 (0.6)	12 (1.4)	0.0441
Deep Vein Thrombosis (%)	68 (2.6)	26 (3.0)	0.5775
Urinary Tract Infection (%)	101 (3.8)	37 (4.3)	0.6236
Renal Insufficiency (%)	19 (0.7)	19 (2.2)	0.0009
Myocardial Infarct (%)	21 (0.8)	12 (1.4)	0.1528
Cardiac Arrest Requiring CPR (%)	18 (0.7)	10 (1.2)	0.1874
Bleeding Within 72 Hours (%)	642 (24.5)	213 (24.8)	0.8947
Postoperative Sepsis (%)	197 (7.5)	66 (7.7)	0.9312
Postoperative Septic Shock (%)	65 (2.5)	46 (5.3)	<0.0001
Return to Operating Room (%)	154 (5.9)	63 (7.3)	0.1463
Death (%)	52 (2.0)	28 (3.3)	0.0420

Key: n: Sample Size, SD: Standard Deviation.

P = 0.01), postoperative septic shock (OR 2.22, 95% CI 1.46–3.38, P < 0.001), pulmonary embolism (OR 2.42, 95% CI 1.07–5.45, P = 0.03), and renal insufficiency (OR 2.67, 95% CI 1.33–5.38, P = 0.005). The obese group also had increased risk of postoperative death (OR 1.68, 95% CI 1.01–2.78, P = 0.04). See Table 3.

Table 3
Outcomes of matched obesity and control.

Outcome	Odds Ratio	95% CI	p-Value
Superficial Wound Infection	1.09	0.84–1.43	0.515
Deep Space Wound Infection	1.58	0.96–2.58	0.0703
Organ Space Wound Infection	1.38	1.07–1.79	0.0128
Dehiscence	1.78	0.95–3.36	0.0738
Pneumonia	1.07	0.71–1.59	0.758
Unplanned Intubation	1.24	0.84–1.81	0.277
Failure to Extubate >48 Hours	1.60	1.09–2.34	0.0153
Pulmonary Embolism	2.42	1.07–5.45	0.0332
Deep Vein Thrombosis	1.22	0.74–1.99	0.437
Urinary Tract Infection	1.10	0.74–1.65	0.628
Renal Insufficiency	2.67	1.33–5.38	0.0058
Myocardial Infarct	0.99	0.91–1.08	0.877
Cardiac Arrest Requiring CPR	1.0	0.92–1.08	0.924
Bleeding Within 72 Hours	1.0	0.91–1.10	0.984
Postoperative Sepsis	0.98	0.73–1.32	0.91
Postoperative Septic Shock	2.22	1.46–3.38	0.0002
Return to Operating Room	1.39	1.01–1.91	0.0461
Death	1.68	1.01–2.78	0.0453

Key: CPR: Cardiopulmonary Resuscitation.

Sensitivity analysis

Sensitivity analysis, in which propensity score matching with a caliper of 0.01 was performed with 795 obese patients matched to 1818 control patients. Good match was confirmed with a maximum absolute standardized difference of 0.071. There continued to be an increased risk of organ space wound infection (OR 1.36, 95% CI 1.05–1.77, $P = 0.02$), failure to extubate after 48 h (OR 1.54, 95% CI 1.05–2.26, $P = 0.03$), postoperative septic shock (OR 2.04, 95% CI 1.34–3.10, $P < 0.001$), and renal insufficiency (OR 2.48, 95% CI 1.26–4.91, $P = 0.009$) in the obese group compared to control. However, risk for return to the operating room (OR 1.25, 95% CI 0.91–1.72, $P = 0.18$), death (OR 1.41, 95% CI 0.85–2.35, $P = 0.18$), and pulmonary embolism (OR 2.28, 95% CI 0.98–5.34, $P = 0.06$) were no longer significantly higher in the obese group compared to control. See Table 4.

Discussion

In this large observational study using a national clinical database, we found that obesity is associated with increased risk of postoperative complications following PD for pancreatic cancer.

Table 4
Outcomes from sensitivity analysis.

Outcome	Odds Ratio	95% CI	p-Value
Superficial Wound Infection	1.1	0.84–1.45	0.5
Deep Space Wound Infection	1.56	0.93–2.59	0.0859
Organ Space Wound Infection	1.36	1.05–1.77	0.0213
Dehiscence	1.54	0.82–2.88	0.177
Pneumonia	1.05	0.71–1.58	0.796
Unplanned Intubation	1.27	0.86–1.86	0.228
Failure to Extubate >48 Hours	1.54	1.05–2.26	0.026
Pulmonary Embolism	2.28	0.98–5.34	0.057[a]
Deep Vein Thrombosis	1	0.61–1.64	1.0
Urinary Tract Infection	1.11	0.74–1.68	0.606
Renal Insufficiency	2.48	1.26–4.91	0.0089
Myocardial Infarct	0.99	0.91–1.08	0.879
Cardiac Arrest Requiring CPR	1	0.92–1.09	0.945
Bleeding Within 72 Hours	1.01	0.91–1.11	0.92
Postoperative Sepsis	1.08	0.80–1.46	0.628
Postoperative Septic Shock	2.04	1.34–3.10	0.0008
Return to Operating Room	1.25	0.91–1.72	0.177[a]
Death	1.41	0.85–2.35	0.182[a]

[a] No longer significant.

Table 5
Patient selection criteria.

Inclusion Criteria	n
Patients NSQIP 2008–2015 ICD 9: 157.0	10,544
CPT Code 48150	4751
Non- Emergency Case	4719
Wound Class 1 or II	4040
No disseminated Cancer	3891
Not missing BMI Data	3877
Not missing Pre-albumin	3583
Not missing total LOS	3578
Not Missing Operative Time	3577

Key: NSQIP: National Surgical Quality Improvement Program, ICD: International Classification of Disease, CPT: Current Procedural Terminology, BMI: Body Mass Index, LOS: Length of Stay.

Past studies have argued that obesity is not a risk factor for developing complications following major surgeries. A prospective analysis of 6336 patients undergoing major general elective procedures did not find an association between obesity and postoperative complications on multivariable regression.[10] In addition, a multi-institutional cohort study in which 2258 patients underwent major abdominal surgery, including oncological resection and pancreatic surgery, identified obesity as a risk factor for wound complications but not for mortality and other morbidity on multivariable analysis. A limitation of this analysis was that it was not limited to a single procedure and disease type.[11] Similarly, a study which identified patients 262 patients that underwent PD and stratified patients as being either normal weight (BMI <25 kg/m^2), overweight (BMI 25.0–29.9 kg/m^2), and obese (BMI $\geq$30 kg/m^2), found that although there were higher rates of complications in the obese group compared to normal weight group (24.2% vs 13.6%), this was not significant ($P = 0.10$).[15]

In contrast to these studies, other multiple single institutional studies have found links between obesity and developing complications for patients that specifically undergo PD for pancreatic cancer.[12,23] This study, which utilizes a national clinical database, demonstrates that obesity is associated with longer operative times, increased risk of organ space infections, failure to extubate, renal insufficiency, and postoperative septic shock. While obesity was associated with increased risk of pulmonary embolism, return to the operating room, and death, these results were not consistent after performing sensitivity analysis.

We found that obese patients undergoing PD are at increased risk of respiratory complications such as failure to wean from the ventilator, and pulmonary embolism. Failure to wean from the ventilator may be a function of obese patients receiving larger fluid volumes during longer operative procedures.[24] Additionally obese patients, due to their habitus, are at greater risk of atelectasis and have reduced pulmonary compliance, and often have other respiratory comorbidities, such as obstructive sleep apnea and obesity hypoventilation syndrome, which can increase the complexity of airway and ventilation management in these patients.[25]

Additionally, our results suggest that obese patients are at much higher risk of developing renal insufficiency and postoperative septic shock. These are novel findings that, to our knowledge, have not been described in the literature. The improved outcomes seen after PD in the recent era thus possibly tied to advances in postoperative critical care.[23] Clinicians should be vigilant that obese patients are at increased risk of developing renal insufficiency and septic shock. Our results showed no difference in total LOS between obese patients and control, which may be linked to the adoption of pathways by many high-volume centers caring for these patients.[26]

There are several limitations to this study. As this was an observational study, our analysis was limited by the data at hand.

Outcomes typically associated with PD, such as pancreatic fistula, delayed gastric emptying, and total blood loss was not available to us. While numerous studies have shown that obesity is linked to developing pancreatic fistulas, ACS NSQIP does not specifically define this outcome.[12,13,27] Although we focused on patients that had resectable pancreatic cancer, we were unable to account for preoperative staging, tumor size or degree of vascular invasion, which might account for differences seen in operative time. We also do not have long-term outcome data, as ACS-NSQIP is limited to 30-day postoperative morbidity and mortality data. However the focus of this study was on short-term morbidity and mortality rate. Additionally, as with all large observational studies, statistical and practical significance do not always correlate. However strengths of this study include the use of a national clinical database with a large sample size, giving increasing confidence that the data is generalizable to the United States.

As the incidence of obesity continues to rise, the likelihood that hepatobiliary surgeons will encounter obese patients with pancreatic cancer amenable to PD will increase. This study provides both the clinicians and patients increased knowledge of the risks associated with obesity in patients undergoing PD for pancreatic cancer.

Conclusion

In this large observational study using a national clinical database, obesity in patients undergoing PD for head of pancreas cancer was associated with increased risk of major postoperative complications. Clinicians should be aware of these increased risks. Prospective studies to identify preoperative and perioperative factors that will mitigate these adverse outcomes are warranted.

Declaration of competing interest

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article. There are no organizations funding this research.

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This project was reviewed by the Institutional Review Board, and was determined to not meet the definition of human subject research according to federal regulations.

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